

3017. Misbranding of Tox Eliminator devices. U. S. v. 1 Device, etc. (and 1 other seizure action). Tried to the court. Judgment for claimant; judgment reversed upon appeal. Decree of condemnation. (F. D. C. Nos. 16687, 17659. Sample Nos. 25466-H, 26665-H.)

LIBELS FILED: July 12 and October 15, 1945, District of Colorado and District of Utah.

ALLEGED SHIPMENT: One of the devices and various circulars were shipped on or about April 2, 1945, by Tox Eliminator Co., Inc., from Los Angeles, Calif., to Denver, Colo., and the other device and various circulars were shipped on or about May 25, 1945, by Glen Albright, agent for the Tox Eliminator Co., Inc., from Denver, Colo., to Price, Utah.

PRODUCT: 2 *Tox Eliminator devices*,¹ at Denver, Colo., and 1 at Price, Utah, together with a number of accompanying circulars entitled "The Modern Scientific Drugless Way to Health" and "The Magic Power of Water."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation "Tox Eliminator" and the words "Tox Eliminator" and "Tox Elimination" appearing in the circulars were false and misleading since they represented and suggested that by use of the article any toxins in the body would be eliminated, whereas such was not the case.

Further misbranding, Section 502 (a), certain statements in the circulars were false and misleading since the article would not fulfill the promises of benefit stated and implied by such statements.

The false and misleading statements are set forth in the court opinion below.

DISPOSITION: J. O. Wolvin, trading as the Tox Eliminator Co., Inc., appeared as claimant and filed answers denying that the devices were misbranded. Thereafter, the libel actions were consolidated for trial in the District of Utah. The trial commenced on January 17, 1946, before the court without a jury. On January 21, 1946, after consideration of the evidence and arguments of counsel, the court handed down its findings of fact and conclusion of law, the nature of which are set forth in the court opinion below; and on the basis thereof, the court entered a decree in favor of the claimant. Upon denial of the government's motion for a new trial, an appeal was taken to the United States Circuit Court of Appeals for the Tenth Circuit, and on February 27, 1947, the following opinion was handed down by that court:

HUXMAN, *Circuit Judge*: "The government has appealed from the judgment of the United States District Court for the District of Utah denying its prayer for the seizure and condemnation of two certain devices, each bearing a plate reading 'Tox-Eliminator Tox Eliminator Co. Inc. Glendale, Calif. Ser. No. 513' and for the seizure of certain circulars which accompanied the devices. The devices are identical, differing only as to the number of the name plate attached thereto. The action was instituted under the Federal Food and Drug Act, 21 USCA 301 et seq.¹ Trial was to the court, and judgment was entered dismissing the libel.

¹ The applicable statutes are as follows: 321 "(h) The term 'device' * * * means instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

321 "(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"Sec. 352. Misbranded drugs and devices.

"A drug or device shall be deemed to be misbranded * * *.

"False or misleading label—

"(a) If its labeling is false or misleading in any particular."

"The parties stipulated that the sale of the two devices in question had been made, one to a doctor of naturopathy and the other to a doctor of chiropractic, and that the devices were displayed in the places of business of these two men for the purpose of selling the service of the devices, and that the devices were displayed together with certain circulars extolling their merits, and that both the device and the circulars had been transported in interstate commerce.

"The device is described as a colonic irrigator. It differs from the ordinary enema device in that it has an inflow and an outflow tube. The inflow tube is equipped with a thermostatic valve by which the temperature of the water can be regulated, and a pressure valve which limits the pressure of the water entering the body to forty inches. The outflow tube has a transparent arrangement by which the contents coming from the bowels can be seen and observed as they leave the body. One of the circulars involved was labeled 'The Modern Scientific Drugless Way to Health,' and the other was called 'The Magic Power of Water.'² The device is attached to an ordinary water faucet while in use,

² These two circulars in part read as follows:

"The Magic Power of Water.

"From 58 to 65 per cent of the human body is water.

"The bones have only 22 per cent, but the liver contains 69 per cent, muscles 75 per cent, and the kidneys as much as 82 per cent.

"The inside of the cells is fluid and consists largely of a solution of various substances in water. Bodily activity depends on aqueous solutions. Water is used to flush away the waste products of cell activity.

"Water furnishes a medium for digestion, absorption, metabolism (chemical change within the body in nutrition and secretion), and excretion. All these processes, chemical or physical, can take place only in the presence of water. Water is the vehicle for transportation of food, waste, hormones (internal secretions), gases, etc.

"Water is taken into the body not only with our drink but with nearly all foods; fresh meat and vegetables average about 75 per cent of water. It is absorbed mainly from the small intestine.

"By means of the lungs, skin and kidneys we eliminate water. There is a tube, leading out of each kidney, down which there runs a continual trickle of water, carrying dissolved in it the waste substances which have been separated from the blood.

"Air contains oxygen which enters the blood stream through the lungs and revitalizes it. A pure blood stream is a prime essential to health. By means of water and air poisonous waste matter is eliminated through the bowels, kidneys, lungs, skin and liver.

"Tox Elimination is a new method of treatment for disturbed bowel conditions using Nature's agencies, water and air. It is astonishingly effective in a wide variety of cases where all other treatments have failed. Come and see for yourself what Nature's magic powers, properly employed can do for you. If the examination shows your case to be one which requires the services of the Tox Eliminator, a demonstration treatment will be given. If you are not entirely convinced, there will be no charge. . . .

"10 Points of Tox Elimination.

"This natural and drugless therapy assists in accomplishing the following:

"1. Cleansing the colon, thoroughly and in a harmless manner.

"2. Massaging the bowel and helping give necessary tone to tissues involved.

"3. Helps to purify the blood stream; proved by microscopic examination after treatments.

"4. Assists in relieving rheumatic, arthritic and neuritic pain.

"5. Helps reduce hypertension or high blood pressure, thus easing the work of the heart and freeing its cells, and the brain, from undue strain.

"6. Helps to lessen the extra burden which is thrown on the liver and kidneys by improper elimination.

"7. Assists and improves sinus and antrum complications.

"8. Helps in re-establishing a normal peristalsis or natural muscular activity of the intestines.

"9. Helps improve the complexion, by assisting in eliminating the causes of pollution of the blood stream.

"10. Helps in preventing the hardening of the arteries, by minimizing the deposits of calcium and magnesium salts on arterial wall. . . .

"Tox Elimination is a remarkable new treatment that cannot be compared with any other. I firmly believe this instrument will enable me to more thoroughly cleanse the colon of disease-producing waste than is possible by any other method.

and uses water coming from water mains. Much of the controversy centers around the representations contained in these two circulars.

"A pulsating stream of water and air bubbles is introduced into the bowel in a scientifically controlled manner. This pulsating stream penetrates readily into the impacted colon, hitherto inaccessible to most any other method of treatment. A sluggish or diseased colon is a contributing cause of most ailments.

"The air, oxygen and water loosen and dissolve the coats of mucus and stale and encrusted fecal matter that adheres to the walls of the large bowel—in many instances causing it to become distended or ballooned.

"When the liver, colon and kidneys are not in perfect order they cannot do their work properly and as a result toxins are not properly discharged and are carried by the blood to every part of the body, tissues, joints, sinus, appendix, gall bladder and so on.

"Drugless methods, by removing the disease-producing materials at their foundation head, helps the body to stop further damage and rebuild the affected parts and restore them to normal. Causes of irritation and numerous infections are removed. . . .

"The Modern, Scientific, Drugless Way to Health.

"My policy of keeping abreast of latest developments and providing my patients with the very best science has to offer in the treatment and relief of disease has made it necessary for me to adopt a remarkable new instrument to assist in getting at the very bottom and basic cause of a large number of ailments that have heretofore resisted the very best efforts of all branches of healing.

"When the colon is not functioning properly, the small intestine, stomach and the entire digestive tract are sure to be affected.

"I believe this new instrument, the Tox Eliminator will enable me to more thoroughly cleanse the colon than is possible by any other method ever before conceived. The bowels are part of Nature's medium for eliminating poisons from the system. When these poisons have been removed, the blood stream becomes purified and performs its marvelous function of healing and correcting in all parts of the body.

"I investigated this instrument thoroughly before installing it, and in all my years of practice have never before been so impressed by any method of treatment. The results are positively astonishing. If you have tried everything else without relief, you have a surprise in store for you. You really can benefit greatly and not only feel the improvement at once but can actually see with your own eyes the positive evidence of what is causing your trouble. . . .

"Let me impress you with some great truths. Curing is done by the blood stream. Medicines and treatments are effective only when they cause the system to purify the blood stream. Most ailments arise through toxins being thrown into the blood stream and a large share of this comes from the bowels.

"Polluted blood that helped cause an ailment, obviously cannot cure it.

"The bowels are one of Nature's chief agencies for purifying the blood stream. Hence, a thorough cleansing of the colon is helpful toward regaining health.

"And here is the most important of all. . . .

"A thorough cleansing of the colon is not possible through any other means than Tox Elimination. Laxatives often inflame the bowel walls and leave a coating of infectious matter. Enemas and many types of colonic treatment often only partially cleanse the bowel. A daily bowel movement means absolutely nothing as to the condition of the intestinal tract.

"The following are some of the ailments almost invariably accompanied by intestinal toxemia and which respond to Tox Elimination plus such other treatment as your condition requires :

"Arthritis, rheumatism, neuritis, high and low blood pressure, toxic heart conditions, ulcers of stomach and bowels, colitis, chronic appendicitis, gall bladder and liver troubles, kidney and bladder troubles, asthma, migraine, toxic skin troubles, lumbago, and a host of ills that have heretofore been obscure.

"Improper function of the colon is the most frequent contributing cause of intestinal toxemia and the following accompanying symptoms and ailments. They can now be successfully treated by our methods.

"Arthritis, Asthma, Colitis, Constipation, Excessive Fatigue, Foul Breath, Headache, Gall Bladder complications.

"High and Low Blood Pressure, Indigestion, Irregular Heart, Kidney and Bladder Complications, Liver Complications, Lumbago, Menopause Disturbances, Muddy or Pimply Complexion, Migraine.

"Nervousness, Pruritus Ani, Rheumatism, Sinus Trouble, Run Down Condition, Shortness of Breath, Sleeplessness, Ulcers of Colon."

"The government's case was based upon the testimony of five medical experts whose qualifications in their respective fields stand admitted. They testified that while they had never used the device or had never seen it in use, they understood fully the principles upon which it operated, namely, the washing out of the colon by forcing a stream of pulsating water into the intestines. They explained in considerable detail the physiology of the human system, as well as the causes of many of the diseases listed in the circulars, and the treatments therefor where known. They admitted that the causes of a number of the diseases of the body listed in these circulars were still unknown, and that the treatment therefor was not definitely catalogued. They testified that intestinal toxemia, referred to in the circular, was not a condition known to medical science. While admitting that the fecal matter in the colon contained some toxin, they testified that toxins are not absorbed in any considerable quantity into the blood stream from the colon. They denied emphatically that washing out the colon would purify the blood stream. They testified further that such toxins as entered the blood stream from the colon went first to the liver where they were rendered harmless. They testified that the function of the colon had very little, if anything, to do with the numerous diseases mentioned in the circular. They also testified that a colonic irrigation would not cure hardening of the arteries, migraine, lumbago colitis, gall bladder complications, high or low blood pressure, irregular heart, rheumatism, or any of the other named diseases. They testified that enemas or colonic irrigations are helpful in a limited sense only to relieve temporary discomfort caused by severe impaction, or as a preparation in case of some major abdominal surgical operations, but that colonic irrigations do not and cannot constitute an appropriate treatment for any of the diseases listed in the circulars.

"The defense, on the other hand, offered the testimony of Dr. Neal Bishop, a doctor of chiropractic, and of J. O. Wolvin, a layman who was the manufacturer and distributor of the device in question. Dr. Bishop testified that the statements in the circulars were true; that he had treated patients with the device in connection with other therapy, such as chiropractic adjustments, diathermy and others, and that its use was helpful. He did not testify specifically that its use had effected a cure in a single case of any of the diseases enumerated in the circulars. Certain X-rays which he had taken of patients before and after using the device were introduced to show, according to his contention, improved conditions in the posture and texture of the colon. Wolvin testified that the use of the device had cured him of a chronic case of asthma, and that when the asthma had a tendency to recur, his use of the device eliminated it. The only other evidence offered by the defense consisted of excerpts from several medical books, only one of which stated that colonic irrigation would aid in the treatment of any of the diseases named in the circular, other than some diseases of the colon. This in substance is the testimony upon which the judgment appealed from is based.

"The excerpts from these medical books were introduced by the defense over the objection of the government. The court made the following findings of fact and conclusions of law:

FINDINGS OF FACT

"(1) That the libellant has not offered any substantial evidence upon which to entitle it to judgment as prayed.

"(2) That the plate affixed to the colonic irrigator described in each of the labels of information and bearing the serial number and the words 'Tox-Eliminator-Tox-Eliminator Co.' does not constitute misbranding or mislabeling as set out in said Labels, or otherwise.

"(3) That the literature offered and received herein as exhibits 1, 2, 3, and 4, and by this reference made a part hereof, constitutes labeling as such word is defined under Section 321 (m), Title 21 of the USCA.

CONCLUSION OF LAW

"As conclusion of law from the foregoing facts the court finds that the relief prayed for by the libellant in these proceedings should be and is denied. . . .

"In general, the assignments of error present two issues which may be summarized as follows: First, the court erred in admitting in evidence excerpts from the medical treatises offered by the defendants. Second, the court's

findings of fact are contrary to the clear weight of the evidence, and therefore erroneous.

"While the authorities are not in complete accord, the weight of authority is that medical books and treatises are not admissible to prove the statements therein contained.³ The trial court erred in admitting and receiving in evidence excerpts from these books offered by the defendants for the purpose of establishing the truth of the statements contained therein.

"While the trial court did not exclude the testimony of the five medical experts offered by the government, it was of the apparent opinion that their testimony was entitled to no consideration because they had neither tested the device in question nor had they observed it in operation. The court stated: '... my impression is that the government cannot come in here and rely upon the bald opinion of anybody who has never experimented with the thing in question. . . . So I am inclined to hold in this case that the government has failed to produce substantial proof of its charges . . . based upon, as I view it, reliance solely upon the opinion of the medical men.' In other words, the court refused to consider the testimony of the medical experts because he did not consider them qualified to testify concerning this device. Only in this way could the court have made Finding No. 1, 'That the libellant has not offered any substantial evidence upon which to entitle it to judgment as prayed.'

"That these medical experts were competent and qualified to testify as to matters in issue is clear. They were not disqualified merely because they had not used the device in question or had not seen it in operation. They testified not only that they were conversant with colonic irrigation, but also that they were familiar with the principles of the particular device in question. In its fundamentals, this device is not essentially different from any other circulatory apparatus for the purpose of giving an enema. The main function of all such devices is to introduce a flow of water into the colon for the purpose of cleansing it of accumulated waste matter. The fact that this device has a thermostatic control, a pressure valve, and may be attached to a faucet or may force the water further into the colon, in no wise changes its essential or general functions. Being fully conversant with the principles of colonic irrigation and with the principles upon which this device operated, the testimony of these medical experts was competent⁴ and constituted substantial evidence.

"Ordinarily an ultimate finding of fact by a trial court is binding upon the appellate court if sustained by the record, but if the finding is clearly erroneous or is based upon a misapplication of law to evidentiary findings, it is not binding upon the appellate court.⁵

"The trial court's Finding No. 1. 'That the libellant has not offered any substantial evidence upon which to entitle it to judgment as prayed,' is clearly erroneous and must therefore be set aside.

"The court's finding that the plate attached to the device and bearing the words 'Tox Eliminator-Tox Eliminator Co., Inc., Glendale, Calif. Ser. No. 513' does not constitute misbranding or mislabeling, finds support in the record when such label is considered separate and apart from the circulars in question. There is evidence that a colonic irrigation does eliminate some toxins from the colon. Under such testimony, a machine called a tox eliminator which tends to remove some toxins is not misbranded. The court found that the two circulars in question constituted labeling as defined in the Act. It did not, however, make a separate finding whether the statements contained therein were true or constituted mislabeling. It must, however, have been of the opinion that it did not constitute mislabeling, otherwise it could not have concluded as a matter of law that the relief prayed for should not be granted.

"In order for the government to prevail, it was not necessary to prove that all the representations in the two circulars were false. The charge of mislabeling

³ U. P. Ry. Co. v. Yates, 79 F. 584; Miss. Power & Light Co. v. Whitescarver, 68 F. 2d 928; U. S. v. 50¾ Doz. Bottles, Sulfa-Seb. 54 F. Supp. 759; Annotations 65 ALR 1102; 20 Am. Jur., Evidence, Sec. 968; 32 C. J. S., Evidence, Sec. 718.

⁴ Irwin v. Federal Trade Comm., 143 F. 2d 316; U. S. v. 11¼ Doz. Packages, etc., 40 F. Supp. 208.

⁵ U. S. v. Armature Rewinding Co., 124 F. 2d 589; Bratt v. Western Air Lines, 155 F. 2d 850; Sears, Roebuck & Co. v. Talge, 140 F. 2d 395; Bailey v. Smith, 14 F. 2d 519.

would be established if the evidence proved any one of the representations to be false.⁶ Here the substantial evidence by the government establishes the falsity, with minor exceptions, of practically every one of the broad claims set up in these circulars. The defendants offered positive evidence only as to one claim—asthma. One witness testified that the tox eliminator cured his asthma. No attempt was made to refute or contradict the government's evidence as to each of the other claims. The mere statement by Dr. Bishop that he had obtained good results from use of the device does not overcome the positive evidence of the medical experts. It must therefore be conceded that the government has established the falsity of many of these claims not only by the greater weight of evidence but also by all the evidence in the record. The finding of the trial court accordingly should have been that the two circulars in question constituted mislabeling.

"The objection is not to the use of this device or that it does not have a useful place in the art of healing. The vice is in the way and manner in which it is represented and the claims which are made for it in these circulars, which under the stipulation of facts and findings of the court constitute a part of the labeling of the device. For the purpose of this opinion, it may be conceded that its use in flushing out the colon under expert supervision has a tendency to eliminate some toxins therefrom, thus preventing their entrance into the blood stream and thereby contributing somewhat to the purification of the blood and thus, in the ultimate, contributing to some extent to improvement in general health. But this is not what the labeling circulars state. In effect, they hold the machine out as a cure-all for all the ills that affect the human body. The authors of this literature apparently borrowed a leaf from the book of the ancients, who wanted to appease all the gods by erecting a statue to them and who, when they had erected a statue to all of the known gods, then, fearing that they might have overlooked one, erected another statue to the unknown god. Thus, the authors of 'The Modern, Scientific Way to Health,' after naming all the known ills of the body and representing that they would respond to the use of the tox eliminator, added this phrase, 'and a host of ills that have heretofore been obscure.' Nothing is overlooked. Relief is promised from every ill, whether known or unknown.

"It may be argued that the circulars do not promise a full cure in all of these cases, but only relief and improvement. But, as stated by the Supreme Court, 'Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the Act.'

"A casual reading of the circulars is sufficient to establish beyond doubt that the statements in these circulars would induce and were intended to induce the belief in the minds of many of the ailing and suffering that the tox eliminator promised absolute and general relief from all their ailments. The circulars are inherently dishonest and deceiving and constitute misbranding within the meaning of the Act. The government established its case by substantial and preponderant evidence and is entitled to prevail. It follows that Finding No. 1 has no support in the record and must be set aside. This finding of the trial court is therefore set aside, and the judgments are severally REVERSED, and the causes are remanded with directions to proceed in conformity with the views expressed herein."

Pursuant to the foregoing opinion, the matter came on for hearing before the United States District Court for the District of Utah, upon motion of the Government for summary judgment. No appearance was made on behalf of the claimant, and, accordingly, on October 9, 1947, judgment of condemnation was entered. The court ordered that the devices and circulars be destroyed, unless the claimant should bring the two devices into compliance with the law

⁶ Goodwin v. U. S., 2 F. 2d 200.

⁷ U. S. v. 95 Barrels of Vinegar, 265 U. S. 438.

within a period of 60 days. One of the devices was destroyed on February 23, 1948, and the other device was destroyed on May 20, 1948.

9018. Misbranding of Pur-Ar-Lite Air Purifiers. U. S. v. 71 Devices * * * .
Tried to the court. Verdict for Government. Decree of condemnation.
(F. D. C. No. 27260. Sample No. 55219-K.)

LIBEL FILED: June 1, 1949, District of Kansas.

ALLEGED SHIPMENT: On or about March 8, 1949, by the Circlite Corp. from Chicago, Ill.

PRODUCT: 71 *Pur-Ar-Lite Air Purifiers* at Kansas City, Kans. Examination showed that the device consisted of a Sylvania 4W No. S1119 bulb, together with the necessary electrical connections.

LABEL, IN PART: "The Pur-Ar-Lite Air Purifier."

NATURE OF CHARGE: Misbranding, Section 502(a), the following statements, which appeared in accompanying leaflets entitled "Look" and "Here It Is," were false and misleading since the device was not effective in the prevention of the diseases and conditions stated and implied: (In leaflet entitled "Look") "Pur-Ar-Lite * * * protects your family, your home from deadly air-borne bacteria * * * Guards Your Family Against Disease! Yes! Pur-Ar-Lite Air Purifier's powerful concentrated ultra-violet rays quickly, instantly deal a death blow to menacing air-borne germs which spread colds, sore throats, flu, pneumonia, measles, scarlet fever, diphtheria, smallpox and other dread contagious diseases! Pur-Ar-Lite Air Purifier is a modern scientific method of insuring your family's health! * * * In the Bedroom * * * helps protect you and your child against colds, dangerous diseases, cuts down on doctor bills!" and (in leaflet entitled "Here It Is") "In The Bedroom * * * helps protect children and adults from colds, dangerous diseases, cuts down on doctor bills!"

DISPOSITION: The Circlite Corp. appeared as claimant and filed an answer denying that the devices were misbranded. On November 2, 1949, the case came on for trial before the court without a jury, and at the conclusion of the testimony the court made the following findings of fact and conclusions of law in favor of the Government:

HILL, District Judge:

FINDINGS OF FACT

"(1) The Claimant, Circlite Corporation, of Chicago, Illinois, shipped in interstate commerce from Chicago, Illinois, to Kansas City, Kansas, the articles of device seized in the action.

"(2) Said devices were labeled in part 'Pur-Ar-Lite Air Purifier,' and each consisted of a 4-watt mercury arc lamp together with its associated starting and operating components mounted in a metal housing and arranged such that the radiant flux from the lamp was reflected through an opening at one end of the housing. The lamp emitted ultraviolet radiation and on testing the measured density was found to be 44.2 microwatts per square centimeter at 6 inches from the opening and 12.4 microwatts per square centimeter at 12 inches from the opening.

"(3) The labeling which accompanied the devices represented among other things that the use of one of the devices would be effective in killing air-borne bacteria and would be effective in preventing colds, sore throats, flu, pneumonia, measles, scarlet fever, diphtheria, smallpox and other contagious diseases, and would protect one's family and cut down on doctor bills.

"(4) In an average size room the number of air-borne bacteria that the device might kill would be insignificant. The ultraviolet radiation from one of the devices would have no effect in preventing the specific disease conditions for